E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0453; FRL-9816-01-OCSPP]

Thiamethoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thiamethoxam in or on pineapples. Syngenta Crop Protection, LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0453, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and for the OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency,

1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the *Federal Register*'s e-CFR site at *https://www.ecfr.gov/current/title-40*.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0453 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE

FEDERAL REGISTER]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0453, by one of the following methods:

• *Federal eRulemaking Portal*: *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of August 24, 2021 (86 FR 47275) (FRL-8792-02-OCSPP) EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E8908) by Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested to establish a tolerance in 40 CFR part 180.565 for residues of the insecticide, Thiamethoxam {3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine} and its metabolite [N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N'-nitro-guanidine], in or on pineapple at 0.03 parts

per million (ppm) and 0.05 ppm for pineapple, process residue. That document referenced a summary of the petition prepared by Syngenta, the petitioner, which is available in the docket, *https://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing the tolerances at different levels than requested. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Tolerances for residues of thiamethoxam are listed in 40 CFR 180.565 and are expressed in terms of the combined residues of the insecticide thiamethoxam and its metabolite CGA-322704. Metabolite CGA-322704 is also the registered active ingredient clothianidin (tolerance listings in 40 CFR 180.586). Clothianidin (hereinafter referred to as CGA-322704) has a complete toxicological database and appears to have effects in mammals that are different from those of thiamethoxam. A separate risk assessment that addresses risks from CGA-322704 residues resulting from the direct application of CGA-322704 (clothianidin), as well as risks from residues of CGA-322704 coming from thiamethoxam uses has been conducted, and there

are no risk estimates of concern as a result of the proposed tolerance for thiamethoxam residues in imported pineapple. This document entitled, "Clothianidin. Human Health Risk Assessment to Address Exposure Associated with a New Tolerance for Thiamethoxam" can be found at *https:www.regulations.gov* in docket ID number EPA-HQ-OPP-2021-0453.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for thiamethoxam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with thiamethoxam follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for thiamethoxam, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to thiamethoxam and established tolerances for residues of that chemical. EPA is incorporating previously published sections from that rulemaking as described further in this rulemaking, as they remain unchanged.

A. Toxicological Profile

For a discussion of the Toxicological Profile of thiamethoxam, see Unit III.A. of the thiamethoxam tolerance rulemaking published in the *Federal Register* of February 15, 2017 (82 FR 10712) (FRL-9957-00).

B. Toxicological Points of Departure/Levels of Concern

For a summary of the Toxicological Points of Departure/Levels of Concern for

thiamethoxam used for human risk assessment, see Unit III.B. of the February 15, 2017, thiamethoxam tolerance rulemaking.

C. Exposure Assessment

Much of the exposure assessment remains the same although updates have occurred to accommodate exposures from the petitioned-for tolerances. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, please reference Unit III.C. of the February 15, 2017, rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposure from the new use of thiamethoxam on imported pineapple. The acute assessment is based on tolerance-level residues and assumes 100 percent crop treated (PCT); the acute assessment is unrefined. The chronic assessment is based on average residues from crop field trials (except for tolerance-level residues in pineapple commodities) and assumes 100 PCT; the chronic assessment is partially refined. The assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 4.02. EPA with 2005-2010 food consumption information from the United States Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA).

Anticipated residue and PCT information. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Drinking water exposure. EPA has revised the thiamethoxam drinking water assessment since the February 15, 2017, final rule. Based on the Pesticide in Water Calculator's (PWC) version 1.52, the estimated drinking water concentrations (EDWCs) of thiamethoxam in groundwater are 65 parts per billion (ppb) for acute exposures and 58 ppm for chronic exposures. Groundwater EDWCs were used in the dietary assessment for all sources of drinking water.

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." In 2016, EPA's Office of Pesticide Programs released a guidance document entitled "Pesticide Cumulative Risk Assessment: Framework for Screening Analysis." The Agency has utilized this framework for thiamethoxam and determined that thiamethoxam along with clothianidin, acetamiprid, dinotefuran, imidacloprid, nithiazine and thiacloprid form a candidate common mechanism group (CMG). This group of pesticides, referred to as neonicotinoids, is considered a candidate CMG because they share characteristics to support a testable hypothesis for a common mechanism of action for neonicotinoids.

Following this determination, the Agency conducted a screening-level cumulative risk assessment consistent with the 2016 guidance document. The current screening assessment indicates that cumulative risk estimates for neonicotinoids are below the Agency's levels of concern. A detailed description of the cumulative screening assessment can be found in the Neonicotinoid Cumulative Screening Risk Assessment Memo (M. Perron *et al*., DP460743, 3/01/2021). No further cumulative evaluation is necessary for thiamethoxam.

D. Safety Factor for Infants and Children

EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the February 15, 2017, rulemaking for a discussion of the Agency's rationale for that determination.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 12% of the aPAD for children 1 to 2 years old, the population subgroup with the highest exposure. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 73% of the cPAD for children 1 to 2 years old, the population subgroup with the highest exposure.

EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 130 for adults, 160 for children older than 6 years old, and 340 for children less than 6 years old. Because EPA's level of concern for thiamethoxam is an MOE of 100 or below, short-term aggregate risks are not of concern. Because there is no intermediate-term expected residential exposure, the intermediate-term risk has not been assessed. Dietary exposure is the only relevant route of exposure for chronic durations; therefore, the chronic dietary risk is the same as the overall aggregate risk for thiamethoxam and is not of concern. Thiamethoxam is classified as "Not likely to be carcinogenic to humans"; therefore, EPA does not expect thiamethoxam exposures to pose an aggregate cancer risk.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to thiamethoxam residues. More detailed information on this action can be found in the document entitled, "Thiamethoxam. Human Health Risk Assessment for Use on Imported Pineapple" in the docket ID number, EPA-HQ-

OPP-2021-0453.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the February 15, 2017, rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

Codex has established an MRL for thiamethoxam in pineapple at 0.01 mg/kg which is different than the U.S. tolerance. At this time, the Codex and EPA residue definitions are different (Codex's MRL is for the parent compound, thiamethoxam only, while EPA's is thiamethoxam plus metabolite CGA-322704); therefore, it is not possible to harmonize with the Codex MRL.

C. Revisions to Petitioned-For Tolerances

The tolerance on pineapple is being set at 0.04 ppm and pineapple, process residue at 0.06 ppm instead of the proposed levels of 0.03 and 0.05, respectively. The petitioner used only thiamethoxam residues as inputs for the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedure. Using both thiamethoxam and its metabolite CGA-322704 for the input data set results in recommended tolerances of 0.04 ppm for pineapple and 0.06 ppm for pineapple, process residue.

V. Conclusion

Therefore, a tolerance is established for residues of thiamethoxam, including its metabolites and degradates, in or on pineapple at 0.04 ppm and in or on pineapple, process

residue at 0.06 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255,

August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides, and pests, Reporting and recordkeeping requirements.

Dated: June 9, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.565, amend paragraph (a) by designating the table as "Table 1 to Paragraph (a)" and adding in alphabetical order the entries "Pineapple[1]" and "Pineapple, process residue[1]" to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * * * *	
Pineapple[1]	0.04
* * * * * * *	
Pineapple, process residue[1]	0.06
* * * * * * *	

[1] There are no U.S. registrations for these commodities as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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[FR Doc. 2022-12880 Filed: 6/14/2022 8:45 am; Publication Date: 6/15/2022]